K093809

VIDAR systems corporation
The Image of Reliability

510(k) Summary

JAN - 7 2010

Submitter: VIDAR Systems Corporation
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Official Correspondent: Carrie L. Brancart

Date of Submittal: November 30, 2009

Trade Name: Dental Film Digitizer

Common Name: X-Ray Film Digitizer

Classification Name: Medical Image Digitizer (21CFR892.2030)

Product Code: LMA
Predicate Device: Trade Name: Vidar Sierra (P111), TeleRADPro and VXR-12 plus Film Digitizers
510(k): K993597

Manufacturer: VIDAR Systems Corporation

Device Description:

The Dental Film Digitizer is a medical device used to convert x-ray films into a digital format. The device uses high end imaging components and design characteristics specifically geared towards the complexity of x-ray film data; offering the user a low noise, high resolution reproduction of the medical film.

Intended Use:

The VIDAR dental film digitizer is used for making digital copies of x-ray film commonly used in dental practices. Images captured with this device are intended for use in primary, secondary and over-reading applications. The target users of the device are medical professional or trained staff.

Technological Characteristics:

The VIDAR Dental Film Digitizer offers a high optical resolution of 300 dpi; 16-bit grayscale, optical density sensitivity (DMAX) of 4.1 OD, and a medical OD range of 0.2 – 3.6 (incorporates noise and linearity measurements).

Performance Testing:

VIDAR conducts extensive performance testing and the test results demonstrate the device meets the requirements for its intended use. Please see Section 19 Bench Testing.

Substantial Equivalence to Predicate Device:

The VIDAR Dental Film Digitizer is substantially equivalent to the VIDAR Sierra (P111), TeleRADPro and VXR-12 plus Film Digitizers. The comparison table of the principal characteristics of the two devices is shown in Section 13 and specification data for the VIDAR Dental Film Digitizer is included in Section 12.

Conclusion:

In terms of intended use, function, safety, operating environmental conditions and effectiveness of the VIDAR Dental Film Digitizer it is determined to be substantially equivalent to the predicate device used for this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN - 7 2010

VIDAR Systems Corporation
% Mr. John Howlett
Head of BSI Medical Device Notified Body
BSI Group Healthcare, British Standards Institution
Maylands Avenue, Hemel Hempstead, Herts HP2 4SQ
UNITED KINGDOM

Re: K093809
Trade/Device Name: Dental Film Digitizer
Regulation Number: 21 CFR 872.2030
Regulation Name: Medical Image Digitizer
Regulatory Class: II
Product Code: LMA
Dated: December 3, 2009
Received: December 9, 2009

Dear Mr. Howlett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093809

Device Name: Dental Film Digitizer

Indications for Use:

The VIDAR dental film digitizer is used for making digital copies of x-ray film commonly used in dental practices. Images captured with this device are intended for use in primary, secondary and over-reading applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093809